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**WHEN BIOPHARMA MEETS SOFTWARE:
BIOINFORMATICS AT THE PATENT OFFICE**

*Saurabh Vishnubhakat & Arti K. Rai**

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I. INTRODUCTION

In 1999, nine years after the National Institutes of Health's ("NIH") National Center for Human Genome Research had published its first joint research plan, the project to sequence the human genome was operating at full force.¹ The entire genome of a free-living organism, *Haemophilus influenzae*, had already been sequenced,² and the first full human chromosome sequence would be published that same year.³ The joint announcement by President Bill Clinton and United Kingdom Prime Minister Tony Blair of the so-called rough draft human genome would be made the following year.⁴

This burgeoning body of genomic knowledge required analytical tools for parsing and manipulating it productively. Though such tools had long existed in computer science and had even been applied to research problems in the life sciences under the designation of bioinformatics, they had not yet been systematized into a formal discipline.⁵ The specialization of such tools to manage the peculiar scope and scale of genomic information marked the origin of bioinformatics as a distinct discipline.⁶

Perhaps not surprisingly, the United States Patent and Trademark Office ("USPTO") had begun receiving a growing number of patent applications for inventions in the field of bioinformatics.⁷ Based on industry input, it projected many more in the coming years.⁸ In re-

1. *A Brief History of the Human Genome Project*, NIH NATIONAL HUMAN GENOME RESEARCH INSTITUTE (Nov. 8, 2012), <http://www.genome.gov/12011239> [<http://perma.cc/B6GW-5X7G>].

2. Robert D. Fleischmann et al., *Whole-Genome Random Sequencing and Assembly of Haemophilus Influenzae Rd*, 269 *SCIENCE* 496, 496 (1995).

3. Ian Dunham et al., *The DNA Sequence of Human Chromosome 22*, 402 *NATURE* 489, 489 (1999).

4. Press Release, The White House Office of the Press Secretary, President Clinton Announces the Completion of the First Survey of the Entire Human Genome: Hails Public and Private Efforts Leading to This Historic Achievement (June 26, 2000), <http://archive.hhs.gov/news/press/2000pres/20000626.html> [<http://perma.cc/T2XQ-L8RH>].

5. In 2000, NIH issued a working definition of bioinformatics which accounted for the utility of the field in the expansive use of available biological information. See *NIH Working Definition of Bioinformatics and Computational Biology*, NIH BIOMEDICAL INFORMATION SCIENCE AND TECHNOLOGY INITIATIVE (July 17, 2000), <http://www.bisti.nih.gov/docs/CompuBioDef.pdf> [<http://perma.cc/RKW9-5G2J>].

6. Jorge L. Contreras, *Implementing Procedural Safeguards for the Development of Bioinformatics Interoperability Standards*, 39 *N. KY. L. REV.* 87, 87 (2012).

7. Douglas Steinberg, *New PTO Unit Examines Bioinformatics Applications*, *THE SCIENTIST* (Nov. 27, 2000), <http://www.the-scientist.com/?articles.view/articleNo/13144/> [<https://perma.cc/C66V-FJHP>].

8. *Id.*

sponse, by December of 1999, the USPTO had established a new art unit to examine all bioinformatics applications in a consistent way.⁹ The art unit resides in USPTO Technology Center 1600,¹⁰ which examines inventions in biotechnology and organic chemistry¹¹ and is designated art unit (“AU”) 1631.¹²

From its earliest days, the patent examiners in AU 1631 had diverse expertise not only in the biological sciences, but also in physics and electrical engineering and, most importantly, computer science.¹³ The USPTO considered the software and data processing patent cases of the late 1990s¹⁴ directly relevant to patents on computing tools for analyzing biological systems, and accordingly advised bioinformatics inventors to draw lessons from the software invention guidelines in the Manual of Patent Examining Procedure (“MPEP”).¹⁵ Thus the rapid expansion of software patentability seen in that era directly affected AU 1631.

However, the art unit was also located in Technology Center 1600, which had just announced important, new, relatively strict examination guidelines on the so-called written description and utility requirements.¹⁶ This latter group of guidelines presumably also had some impact on the behavior of examiners in AU 1631.

This Article analyzes these dual influences in an early cohort of patent applications assigned to AU 1631. It first compares the characteristics of these applications with a comparison group of applications from a related but more traditionally software-oriented data processing art unit, AU 2123. Our analysis shows that on all conventional measures of technological importance, private value and quality, applications in AU 1631 were significantly different from and “better” than applications in AU 2123. To that extent, our results reinforce the empirical theme of considerable variation in the manner in which the system operates across technologies.

The Article then compares the examination of applications from AU 1631 with a matched set of applications from AU 2123. On a sample of applications matched on various dimensions of private val-

9. *Id.*

10. See USPTO, *PATENT TECHNOLOGY CENTERS MANAGEMENT*, <http://www.uspto.gov/web/patents/contacts/tcmgrs.htm> (last visited Dec. 17, 2015).

11. Steinberg, *supra* note 7.

12. *Id.*

13. *Id.*

14. See generally *AT&T Corp. v. Excel Commc’ns Inc.*, 172 F.3d 1352 (Fed. Cir. 1999); *State St. Bank & Tr. Co. v. Signature Fin. Grp. Inc.*, 149 F.3d 1368 (Fed. Cir. 1998).

15. Steinberg, *supra* note 7.

16. Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1 “Written Description” Requirement; Request for Comments, 64 Fed. Reg. 71,427 (Dec. 21, 1999); Revised Utility Examination Guidelines; Request for Comments, 64 Fed. Reg. 71,440 (Dec. 21, 1999).

ue and quality, patent prosecution in AU 1631, with its biology-trained examiners, looked strikingly different from prosecution in AU 2123. With the notable exception of nonobviousness rejections, applications in AU 1631 experienced more rejections, particularly notice-related rejections, than a matched sample of applications in AU 2123.

As we discuss, these differences in patent examination quality, particularly with respect to notice, appear to result from the biotechnology-specific examination guidelines that applied to examiners in AU 1631, as well as the higher educational attainment of these examiners. Our results therefore have implications for improving patent examination quality. Specifically, our results suggest that the various pressures that operate against rigorous examination, including in the area of software, can be countered if properly trained examiners are given notice-enhancing tools that can be applied with relative ease, such as the written description and definiteness requirements.

We conclude by linking our results to the literature discussing how the growing percentage of patent applications that rely on interdisciplinary and team-based science should be examined.

Part II of the Article summarizes the robust debate surrounding patent quality and introduces the issue of measuring quality. Part III surveys the quality metrics that scholars and policymakers have employed in evaluating the USPTO's performance as an *ex ante* guarantor of patent quality. Part IV applies the quality metrics identified in Part III to more than five hundred patent applications from AU 1631 and AU 2123 and discusses the significant differences identified between applications reviewed in these two art units. Part V elaborates on policy implications, both for patent quality and for how patent offices should examine applications that increasingly rely on team-based, interdisciplinary science.

II. QUALITY IN THE PATENT OFFICE

Much of the current dissatisfaction with the U.S. patent system stems from concerns about patent quality. Numerous commentators have put forward proposals for quality improvement.¹⁷ Some of these — most notably, enhanced post-grant adjudications at the USPTO — were incorporated into the America Invents Act of 2011

17. See generally JAMES BESSEN & MICHAEL J. MEURER, *PATENT FAILURE* (2008); DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* (2009); ADAM B. JAFFE & JOSH LERNER, *INNOVATION AND ITS DISCONTENTS* (2004); Stuart Minor Benjamin & Arti K. Rai, *Who's Afraid of the APA? What the Patent System Can Learn from Administrative Law*, 95 GEO. L.J. 269 (2007).

(“AIA”).¹⁸ The court system has acted on others.¹⁹ Even so, more remains to be done.

When critics bemoan poor quality, they are concerned about several different issues.²⁰ These include: failure to comply with the statutory requirement that patents be granted only to inventions that would not be obvious to the ordinary scientist or technologist working in the area;²¹ failure to comply with the statutory requirement that the patent disclose how to make and use the full scope of the invention covered by the claims;²² and violation of the principle that the patent claims must give proper notice as to the boundary of the patent right.²³

Patent quality failures are perhaps most visible in litigation,²⁴ due to patent litigation’s high costs,²⁵ often unpredictable outcomes,²⁶ and

18. Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) (codified in scattered sections of 35 U.S.C.).

19. For example, the Supreme Court in 2007 raised the nonobviousness standard for patentability by enabling patent examiners to combine prior art references and reject inventions as obvious without strict application of the “teaching, suggestion, or motivation” test to make such combinations. *See KSR Int’l. Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007).

20. For present purposes, we avoid the question of whether patents on certain types of inventions are inherently “poor quality.” To be sure, the Supreme Court has clearly held that restrictions should be placed on patent-eligible subject matter. *See, e.g., Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2352 (2014); *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294 (2012); *Bilski v. Kappos*, 561 U.S. 593, 611–12 (2010).

21. *See* 35 U.S.C. § 103 (2012); *KSR*, 550 U.S. at 420 (2007) (finding that a patent on an adjustable automobile pedal assembly would, at the time of invention, have been obvious to one of ordinary skill in the field when considered in light of the available technology).

22. *See* 35 U.S.C. § 112(a) (2012); *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1382 (Fed. Cir. 2009) (affirming that a patent on a method for using immunosuppressant rapamycin drugs to treat and prevent re-narrowing of arteries required excessive experimentation and was therefore invalid under § 112(a) for nonenablement).

23. *See* 35 U.S.C. §§ 112(b), (f) (2012); *In re Packard*, 751 F.3d 1307, 1309 (Fed. Cir. 2014) (affirming the USPTO’s rejection of a patent application on a coin change holder under § 112(b) for indefiniteness); *Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 711 F.3d 1348, 1365 (Fed. Cir. 2013) (finding in pertinent part that patents on techniques for mitigating electromagnetic interference and current flow problems recited sufficient structure with respect to the term “soft start circuit” to satisfy the means-plus-function requirements of § 112(f)). The Federal Circuit has also adopted the view that the written description terminology of § 112(a) performs a notice function. Moreover, as discussed further below, although the court indicated in 2010 that written description applies to all technologies, during the time of this empirical study the requirement only appeared to apply to biotechnology and chemistry. *See Ariad Pharm. et al. v. Eli Lilly & Co.*, 598 F.3d 1336, 1349 (Fed. Cir. 2010) (en banc).

24. *See, e.g.,* Charles Duhigg & Steve Lohr, *Fighters in a Patent War*, N.Y. TIMES (Oct. 7, 2012), <http://www.nytimes.com/interactive/2012/10/08/business/Fighters-in-a-Patent-War.html> [<http://perma.cc/23SS-ZV62>] (summarizing a network of patent lawsuits among the top patent litigants in the smart phone industry since 2006). Controversial litigation arises not only in smartphones and software but also over genes. *See, e.g.,* Brent Kendall, *Myriad Genetics Presses Ahead After High Court Ruling on Patents*, WALL ST. J.: L. BLOG (July 12, 2013), <http://blogs.wsj.com/law/2013/07/12/myriad-genetics-presses-ahead-after-high-court-ruling-on-patents/> [<http://perma.cc/5YVK-B3VV>].

25. Compare James Bessen & Michael J. Meurer, *The Direct Costs from NPE Disputes*, 99 CORNELL L. REV. 387, 390 (2014) (estimating the direct costs to defendants from patent

potentially lasting dynamic losses to innovation.²⁷ Yet because many of the more egregious harms from patent litigation are best understood as effects rather than causes of poor patent quality,²⁸ one important locus of proposed reforms continues to be the USPTO infrastructure for initial patent examination.²⁹

Given the impossibility of systematically evaluating every patent that issues from the USPTO for compliance with novelty, nonobviousness, disclosure, and notice requirements, critics have pointed to various institutional features that would suggest poor quality. One set of institutional features prevents proper application of existing patent law standards. Another set may cause these standards to be too lax. Because both sets of institutional features provide the motivation for our empirical analysis of quality, we discuss them below. We then discuss how these institutional implications vary in technology-specific ways.

assertions by non-practicing entities at about \$29 billion in 2011), with David L. Schwartz & Jay P. Kesan, *Analyzing the Role of Non-Practicing Entities in the Patent System*, 99 CORNELL L. REV. 425, 433 (2014) (critiquing the findings and methodology of Professors Bessen and Meurer as a likely upper bound and potentially biased upward).

26. Both the literature and case law identify a variety of sources for unpredictability in patent litigation. See, e.g., J. Jonas Anderson & Peter S. Menell, *Informal Deference: A Historical, Empirical, and Normative Analysis of Patent Claim Construction*, 108 NW. U. L. REV. 1, 4–7 (2014) (discussing uncertainty in claim construction); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 723 (2002) (explaining that despite the uncertainty that the doctrine of infringement by equivalents introduces into the patent system, the Court has repeatedly accepted such uncertainty “as the price of ensuring the appropriate incentives for innovation”); see also Alan C. Marco & Saurabh Vishnubhakat, *Certain Patents*, 16 YALE J.L. & TECH. 103, 132 (2013) (estimating the economic value of the certainty in patent rights that adjudicative resolution brings).

27. The subject of dynamic and static impacts on innovation from patenting is both widely studied in its own right and widely applied to particular economic and legal situations. For a good overview, see generally Peter Lee, *Toward a Distributive Commons in Patent Law*, 2009 WIS. L. REV. 917 (2009); Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989 (1997); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990); Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSPS., Winter 1991, at 29.

28. Cf. Mark A. Lemley & A. Douglas Melamed, *Missing the Forest for the Trolls*, 113 COLUM. L. REV. 2117, 2120–21 (2013) (arguing that the effects of patent assertion by patent trolls, however defined, are a symptom of systemic flaws in the patent system).

29. The situation post-grant appears to be quite different. Not only are the post-grant review procedures set up by the AIA very heavily utilized, see *AIA Trial Statistics*, USPTO, <http://www.uspto.gov/patents-application-process/appealing-patent-decisions/statistics/aia-trial-statistics> (last visited Dec. 17, 2015) (tabulating usage of the AIA patent validity challenge procedures from April through September 2015), but criticisms center around the idea that the procedures are too strict, not too lax. See, e.g., Ronald L. Grudzicki, *Rapidly Changing Patent Law Landscape Requires Careful Attention from Attorneys*, ASPATORE, May 2015 WL 3764843, at *3 (2015) (noting that the Patent Office “has received numerous complaints regarding amendment proceedings, because some patents probably could have been saved by further amendments, but the USPTO did not provide enough pages for amendment, and the requirements were overly strict”).

A. Improper Application of Patent Law Standards

The USPTO operates under a number of institutional constraints that might cause application of existing patent law standards to be too lax. Perhaps most notably, examiners have a very limited amount of time to examine patents.³⁰ Thus, fact-intensive patent law standards that involve significant work, such as thoroughly searching prior art to evaluate nonobviousness or thoroughly evaluating an application's disclosure, may simply be too burdensome for examiners to implement successfully. Recent empirical work, discussed further in Part III, suggests that these time constraints become particularly restrictive as examiners advance in seniority.³¹

Another reason for concern is the agency's funding structure, which is not only entirely fee-based but also heavily based on fees paid only if a patent is granted.³² The USPTO currently charges \$1600 cumulatively for the filing, search, and examination of patent applications — even though the cost of doing this work is more than double that amount.³³ More generally, in the period from 2001 to 2014, over half of the USPTO's operating budget came from issuance fees that are paid only after an examiner deems a patent application allowable and from maintenance fees that are paid during the post-grant life of the patent; filing, search, and examination fees from new applications accounted for less than a third of the USPTO's annual revenue.³⁴ In fact, some empirical research suggests that categories of patents from which the USPTO is more likely to receive maintenance fees are also

30. See Michael D. Frakes & Melissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence from Micro-Level Application Data 8–9* (Nat'l Bureau of Econ. Research Working Paper No. 20337, 2014), <http://www.nber.org/papers/w20337> [<http://perma.cc/BVC6-FG3R>].

31. See generally *id.*

32. See, e.g., Arti K. Rai, *Growing Pains in the Administrative State: The Patent Office's Troubled Quest for Managerial Control*, 157 U. PA. L. REV. 2051, 2062 (2009) (arguing that the USPTO's fee structure "sets up an obvious financial incentive for the USPTO to grant patents").

33. The USPTO fee schedule for utility applications charges \$280 for filing, \$600 for search, and \$720 for examination, totaling \$1600. *USPTO Fee Schedule*, USPTO (Jan. 1, 2014), <http://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule>. What these activities cost the USPTO to perform, however, is considerably higher. These costs totaled \$3569 in FY 2011, \$3906 in FY 2010, and \$3284 in FY 2009. USPTO, USPTO SECTION 10 FEE SETTING — ACTIVITY-BASED INFORMATION AND COSTING METHODOLOGY 18, http://www.uspto.gov/sites/default/files/aia_implementation/aia_section_10_cost_supplement.pdf (last visited Dec. 17, 2015).

34. From FY 2001 through FY 2014, annual revenues from maintenance and issue fees constituted 50% or more of total annual revenues, whereas annual revenues from filing, search, and examination fees constituted between 24% and 31%. See *USPTO Annual Reports*, USPTO, <http://www.uspto.gov/about-us/performance-and-planning/uspto-annual-reports> (last visited Dec. 17, 2015) (containing hyperlinks to Performance and Accountability Reports from FY 2001–2014).

more likely to be granted.³⁵ In the absence of a specifically-identified mechanism by which motivation for future economic gain might influence current USPTO behavior in particular patent areas, these findings should be viewed cautiously. Nonetheless, given the USPTO's fee structure, applying patentability criteria loosely would have a positive effect on USPTO funding. So would legal or policy decisions that affirmatively relaxed these criteria. In the next section, we examine other institutional pressures that might cause legal standards to be overly lax.

B. Lax Patentability Standards

Even absent substantive rulemaking authority, the USPTO has some ability to articulate the contours of patent law.³⁶ Beyond merely exercising its discretion in the interstitial application of patent law to the facts of patent examination, the USPTO also frequently issues legal guidance documents to its examiners to interpret judicial decisions and produces its own substantive precedents in the agency's internal administrative appeals process.³⁷ Though the Federal Circuit has, thus far, given no deference to these guidance documents or precedents,³⁸ the vanishingly small subset of USPTO actions that come before the Federal Circuit reflects further limitations on the court's ability to actively manage the direction of substantive patent law.³⁹ Moreover, as noted above, the USPTO's funding structure may give it an incentive to relax patentability standards.

Another mechanism by which patentability standards may have become too lax involves the interaction between the USPTO and the Court of Appeals for the Federal Circuit prior to the passage of the America Invents Act of 2011. Prior to the AIA, the major route by which appeals from the USPTO came to the Federal Circuit was

35. Michael D. Frakes & Melissa F. Wasserman, *Does Agency Funding Affect Decisionmaking?: An Empirical Assessment of the PTO's Granting Patterns*, 66 VAND. L. REV. 67, 69–71 (2013).

36. Melissa F. Wasserman, *The PTO's Asymmetric Incentives: Pressure to Expand Substantive Patent Law*, 72 OHIO ST. L.J. 379, 387–89 (2011). See also Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1131–33 (2003) (comparing the relative competencies of the Federal Circuit in judicial patent policymaking and the USPTO in administrative patent policymaking during the early 2000s).

37. Wasserman, *supra* note 36, at 394–98.

38. *Id.* at 383. But see Arti K. Rai, *Improving (Software) Patent Quality Through the Administrative Process*, 51 HOUS. L. REV. 503, 540–43 (2013) (arguing that legal determinations made in post-grant review proceedings set up by the AIA may merit *Chevron* deference).

39. Wasserman, *supra* note 36, at 398–400.

through a decision by an applicant to appeal a rejection.⁴⁰ Thus, the agency could be reversed only for improper rejections and not improper grants. Under a model where the agency was motivated entirely by the fear of Federal Circuit reversal, it would presumably reject only that small subset of applications that were seen as unpatentable even by the most “pro-patent” members of the Federal Circuit. The result would be a progressive lowering of patent standards.

Although this model probably overstates the extent to which the USPTO is motivated by Federal Circuit reversal, and understates the extent to which it is influenced by the White House and by workload fears, the USPTO has, at times, certainly found itself beholden to Federal Circuit decisions that made it very difficult for the agency to deny patents.⁴¹ For example, during the time period covered by our study, the agency operated under a requirement that it show a written teaching, suggestion, or motivation (“TSM”) to combine prior art when making an obviousness rejection.⁴² As we discuss below, this TSM requirement may have had particular force for AU 1631, where prior art from the life sciences and software would presumably sometimes have to be combined to make an obviousness rejection.

C. Quality and Technology-Specificity

The debate over patent quality also has a technological dimension. This dimension is particularly relevant for purposes of our paper, as we explicitly address not simply a “recombinant” field but a field that combines two areas — biotechnology and software — historically considered quite different from a quality perspective.

Although the United States has a unitary patent system with few formal exclusions or exceptions,⁴³ the potentially wide-ranging differences among the economic and legal needs of various technology and industry sectors have made it necessary and appropriate for U.S. patent law to adopt doctrines that accommodate those differences.⁴⁴

Many substantive criteria for patentability operate by reference to a person having ordinary skill in the art (“PHOSITA”), analogous to

40. See Jonathan Masur, *Patent Inflation*, 121 YALE L.J. 470, 503 (2011); Wasserman, *supra* note 36, at 401–06.

41. See generally Arti K. Rai, *Who's Afraid of the Federal Circuit?*, 121 YALE L.J. ONLINE 335 (2011) (discussing the merits of Professor Masur's inflationary model).

42. See *id.*; see also *DyStar Textilfarben GmbH & Co. v. C.H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006); *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002).

43. COMM. ON INTELL. PROP., NAT'L RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY 45 (Stephen A. Merrill et al. eds., 2004).

44. *Id.*

tort law's reasonably prudent person,⁴⁵ and so incorporate technology-specific perspectives into nominally technology-agnostic standards.⁴⁶ The foundational role of the PHOSITA has, for example, resulted in a doctrine of "unpredictable arts" that tolerates in those arts a greater degree of experimentation for purposes of enablement⁴⁷ and more readily accepts unlikely advances over the prior art for purposes of nonobviousness.⁴⁸ Indeed, usage of the PHOSITA construct may itself be so fact-intensive as to produce doctrine that is overly technology-specific,⁴⁹ raising the normative question of how best to identify the PHOSITA.⁵⁰

Beyond the PHOSITA construct, the Federal Circuit's historical tendency to apply the written description terminology of 35 U.S.C. § 112(a) to biotechnology and chemistry, but not necessarily to other arts,⁵¹ had implications for both notice and scope. In the 1997 case of *University of California v. Eli Lilly*, the Federal Circuit held that, even for originally filed claims, written description was a requirement sepa-

45. *Panduit Corp. v. Dennison Mfg.*, 810 F.2d 1561, 1566 (Fed. Cir. 1987) (noting patent law's reliance on "a ghost, i.e., 'a person having ordinary skill in the art,' not unlike the 'reasonable man' and other ghosts in the law").

46. See 35 U.S.C. §§ 103, 112(a), 122(b)(2)(B)(v) (2012). See also Arti K. Rai, *Building a Better Innovation System: Combining Facially Neutral Patent Standards with Therapeutics Regulation*, 45 HOUS. L. REV. 1037, 1045 (2008).

47. See *In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988).

48. See *Procter & Gamble v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 996 (Fed. Cir. 2009).

49. See generally Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155 (2002).

50. See, e.g., Jonathan J. Darrow, *The Neglected Dimension of Patent Law's PHOSITA Standard*, 23 HARV. J.L. & TECH. 227, 240–45 (2009) (arguing that the PHOSITA standard has progressed from the tradesman "who practiced his art with ordinary skill but was not an inventor" to the designer "whose work required a significant effort of the brain" to an inapt researcher model that under-rewards innovation in the useful arts by defining the relevant art itself in terms of innovative activity).

51. See, e.g., *Moba v. Diamond Automation, Inc.*, 325 F.3d 1306 (Fed. Cir. 2003) (per curiam), cert. denied, 540 U.S. 982 (2003). In *Moba*, Judge Rader wrote separately to note, *inter alia*, that the written description requirement as interpreted in the Federal Circuit's jurisprudence had "create[d] a technology-specific rule in a technology-neutral statute." *Id.* at 1327 (Rader, J., concurring). Commentators have agreed with this assessment as well. See, e.g., Burk & Lemley, *supra* note 49; Ajeet P. Pai, *The Low Written Description Bar for Software Inventions*, 94 VA. L. REV. 457 (2008). In contrast, a 2007 paper by Chris Holman uses data from appeals of patent rejections to the internal USPTO appeals board (then called the Board of Patent Appeals and Interferences, or BPAI) to argue that written description has not necessarily played an important role. Christopher M. Holman, *Is Lilly Written Description a Paper Tiger: A Comprehensive Assessment of the Impact of Eli Lilly and Its Progeny in the Courts and PTO*, 17 ALB. L.J. SCI. & TECH. 1 (2007). Holman emphasizes the small number of BPAI decisions that address written description. However, to the extent that written description is a relatively bright-line rule, a rejection that appears correct under the application of that rule may not be appealed at all. E.g., Kate S. Gaudry & Joseph J. Mallon, *Appeals and RCEs — The Frequency and Success of Challenges to Specific Rejection Types*, INTELL. PROP. TODAY, Nov. 2011, at 28 (finding that after a final rejection by the examiner, applicant appeals to the BPAI as well as applicant requests for continued examination relied quite infrequently on § 112 grounds such as written description or enablement).

rate from enablement.⁵² The Federal Circuit also held that a genus claim (in that case a functional genus claim to cDNA that coded for insulin) satisfied written description only to the extent that it included the structure of a subset of species representative of the genus.⁵³ The USPTO's Written Description Guidelines, issued in draft form in 1999 and finalized in 2001,⁵⁴ relied heavily on this precedent, stressing that the structure of a "representative number of species" was necessary to claim the genus.⁵⁵

To the extent that the written description requirement has been applied more to biotechnology and chemistry than to other arts,⁵⁶ it has arguably generated better boundary notice and more appropriately tailored scope in biotechnology and chemistry. Boundary notice in chemistry — though not necessarily in biotechnology — may also reflect the discipline's well-standardized conventions of nomenclature.⁵⁷ In contrast, the relatively imprecise vocabulary of software-related inventions requires greater standardization through bodies, such as the Institute of Electrical and Electronics Engineers ("IEEE").⁵⁸

Additionally, because technology is itself malleable in definition, imposing a priori classifications may compound the already difficult task of comparing patent quality across different arts.⁵⁹ One aspect of this problem is that inventions that are truly seminal in a new field

52. 119 F.3d 1559, 1566 (Fed. Cir. 1997).

53. *Id.* at 1566–69 (invalidating functional genus claim to insulin cDNAs because the written description failed to recite enough species to constitute a "substantial portion of the genus").

54. Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001).

55. *Id.*

56. See Margaret Sampson, *The Evolution of the Enablement and Written Description Requirements under 35 U.S.C. 112 in the Area of Biotechnology*, 15 BERKELEY TECH. L.J. 1233, 1234–36 (2000). However, the Federal Circuit's *en banc* decision in *Ariad Pharm. v. Eli Lilly & Co.*, handed down in 2010, does purport to make written description a requirement that applies equally to all technology. 598 F.3d 1336 (Fed. Cir. 2010) (*en banc*).

57. BESSEN & MEURER, *PATENT FAILURE*, *supra* note 17, at 152–53. But see generally William D. Marsillo, *How Chemical Nomenclature Confused the Courts*, 6 U. BALT. INTELL. PROP. L.J. 29 (1997) (arguing that where a genus of chemical compounds is to be claimed by reference to a few representative species, the rules of chemical nomenclature have created judicial confusion about theoretical permutations of chemical structure and the practical import of actual chemical and physical properties).

58. See Peter S. Menell & Michael J. Meurer, *Notice Failure and Notice Externalities*, 5 J. LEGAL ANALYSIS 1, 36 (2013) (comparing IEEE's efforts in this regard to similar scientific governance provided by the International Union of Pure and Applied Chemistry).

59. For example, what medical researchers may reliably have denoted "oncology" a century ago is now an immensely broad collection of well-developed disciplines defined by affected populations (e.g., pediatric oncology addressing cancer in children and geriatric oncology addressing cancer in the elderly), affected biological systems (e.g., hematology-oncology addressing blood-related cancers), and, in the case of personalized medicine, even individual genomes. Modern science can no longer discuss inventions in the field of oncology.

pose a challenge for measuring quality because, by their very nature, they are quite broad in scope.⁶⁰ Distinguishing broad patents from overbroad patents is difficult.⁶¹ Evaluating the quality of such patents is similarly difficult. Another aspect of the problem is that general-purpose technologies, such as software, serve as platforms for, or inputs into, a wide variety of other fields,⁶² and inventions in these widely adopted arts are not easily identified in objective and replicable ways.⁶³

This general debate over the importance of technology in patent law informs a variety of specific patent quality discussions including proposals for technology-agnostic⁶⁴ and explicitly category-based⁶⁵ reforms alike. Prominent among these proposals is the desire particularly to assess the quality of software-related patents⁶⁶ and to improve it.⁶⁷ These discussions raise a threshold boundary definition prob-

60. See Matthew J. Conigliaro, Andrew C. Greenberg & Mark A. Lemley, *Foreseeability in Patent Law*, 16 BERKELEY TECH. L.J. 1045, 1049–53 (2001) (describing pioneer inventions as distinct from more incremental technological improvements and proposing a heuristic for according due scope and protection to patents on pioneer inventions). But see generally Brian J. Love, *Interring the Pioneer Invention Doctrine*, 90 N.C. L. REV. 379 (2012) (arguing from historical discussion that truly pioneering inventions do not exist and that patent law should formally abrogate the doctrine of giving broad protection to pioneer inventions).

61. See *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1334–38 (Fed. Cir. 2014) (Prost, J., concurring in part, dissenting in part) (discussing the need either to require adequate structural information in the patent or to apply means-plus-function treatment under 35 U.S.C. § 112(f), or else invite problems of overbroad patenting).

62. Stuart J.H. Graham & Maurizio Iacopetta, *Nanotechnology and the Emergence of a General Purpose Technology*, 115/116 ANNALS OF ECON. & STATS. 5, 8 (2014), <http://www.ssrn.com/abstract=1334376> [<http://perma.cc/6S3N-AZU9>]; Stuart J.H. Graham & Saurabh Vishnubhakat, *Of Smart Phone Wars and Software Patents*, 27 J. ECON. PERSPS. 67, 74–75 (2013). See generally Timothy F. Bresnahan & Manuel Trajtenberg, *General Purpose Technologies: “Engines of Growth?”* 65 J. ECONOMETRICS 83, 83–85 (1995) (articulating the characteristics of general purpose technologies).

63. For a discussion of the methodological tradeoffs between reaching an accurate definition of software patents that minimizes Type I and Type II errors and reaching a precise definition that is reproducible despite potential errors, see Bronwyn H. Hall & Megan MacGarvie, *The Private Value of Software Patents* 13–17 (NBER Working Paper No. 12195, May 2006), <http://www.nber.org/papers/w12195> [<http://perma.cc/5H8D-NBR8>]. See also Arti K. Rai, John R. Allison & Bhaven N. Sampat, *University Software Ownership and Litigation: A First Examination*, 87 N.C. L. REV. 1519, 1526–33 (discussing Type I and Type II errors in various definitions).

64. E.g., Jaffe & Lerner, *supra* note 17.

65. E.g., Peter S. Menell, *A Method for Reforming the Patent System*, 13 MICH. TELECOMM. & TECH. L. REV. 487 (2007).

66. See John R. Allison, Abe Dunn & Ronald J. Mann, *Software Patents, Incumbents, and Entry*, 85 TEX. L. REV. 1579, 1581 (2007) (framing proposed reforms for patents on software-related inventions in terms of the “varying uses to which software firms put patents in their businesses”); see also John R. Allison & Ronald J. Mann, *The Disputed Quality of Software Patents*, 85 WASH. U. L. REV. 297 (2007).

67. Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CAL. L. REV. 1, 3–4 (2001) (arguing for ex post tailoring of scope in software-

lem,⁶⁸ which invites general reforms of patent quality that would disproportionately affect patents on software-related inventions in a positive way,⁶⁹ as well as software-specific reforms.⁷⁰

More generally, quality concerns have spawned numerous proposals for reform. Some of these proposals, such as significantly enhanced post-grant review of issued patents, have already been implemented in the AIA. Others, particularly with respect to notice, have yet to be attempted or have been implemented only in pilot form. We defer discussion of future potential reforms to Part V, when we turn to policy implications of our empirical findings.

In the next Part, we review efforts to measure patent quality quantitatively. Although these empirical studies do not necessarily lead directly to specific normative conclusions, they provide important background for our own empirical work.

III. MEASURING PATENT QUALITY

The challenge of describing patent quality in qualitative terms is matched by the challenge of describing and estimating patent quality through quantitative measures. Some of the difficulty arises because the empirical literature has not always distinguished carefully between at least three distinct visions of quality: (1) a patent document that is “important” and facilitates diffusion of knowledge; (2) the private value of a patent to the patent owner; and (3) a patent’s conformance with existing legal criteria for patentability.⁷¹ Additionally, an emerging empirical literature views quality through the lens of examiner characteristics and incentives that affect the rigor of examination.⁷²

Below we review the quantitative measures in the existing literature, with a focus on those measures that will help us evaluate both incoming patent applications to AU 1631 and AU 2123, and the ef-

related patents through a limited right to reverse-engineer as well as a narrow application of the doctrine of equivalents).

68. Colleen V. Chien, *Reforming Software Patents*, 50 HOUS. L. REV. 325, 354–55 (2012) (discussing the problem of defining software patents and noting some of the foundational legal literature on proposed definitions).

69. See generally Rai, *supra* note 38, at 5–8.

70. Kevin Emerson Collins, *Patent Law’s Functionality Malfunction and the Problem of Overbroad, Functional Software Patents*, 90 WASH. U. L. REV. 1399, 1400–02 (2013); Mark A. Lemley, *Software Patents and the Return of Functional Claiming*, 2013 WISC. L. REV. 905, 907–08 (2013).

71. See Ronald J. Mann & Marian Underweiser, *A New Look at Patent Quality: Relating Patent Prosecution to Validity*, 9 J. EMPIRICAL L. STUD. 1, 2–4 (2012) (discussing literature on knowledge diffusion and private value but focusing on legal validity); see also R. Polk Wagner, *Understanding Patent-Quality Mechanisms*, 157 U. PA. L. REV. 2135, 2138–39 (2009) (distinguishing between patent quality and private patent value).

72. See *infra* Section III.D.

fects of examination. As we discuss in Part IV, we have data on the characteristics of incoming applications and on how those applications were examined. At the art unit level, we also have data on a variety of examiner characteristics.

A. Citations and Knowledge Transfer

The literature tabulating forward citations of patents⁷³ stresses the patent's role in diffusing scientific or technical knowledge in a given community. On this view, patents that are highly cited by other patents are likely to be important.⁷⁴ One factor that is positively correlated with forward citation rates, and with technological importance more generally, is the number of co-inventors.⁷⁵ For this reason, in Part IV we use numbers of inventors as one metric for evaluating incoming patent applications.

73. See, e.g., Bronwyn H. Hall, Adam B. Jaffe & Manuel Trajtenberg, *The NBER Patent Citations Data File: Lessons, Insights and Methodological Tools* (NBER Working Paper No. 8498, Oct. 2001), <http://www.nber.org/papers/w8498.pdf> [<http://perma.cc/P4J7-9FDN>]; Adam B. Jaffe, Manuel Trajtenberg & Rebecca Henderson, *Geographic Localization of Knowledge Spillovers as Evidenced by Patent Citations*, 108 Q.J. ECON. 577, 577 (1993). Numerous legal scholars have invoked this work in their own utilization of citation metrics. See, e.g., James Malackowski & Jonathan A. Barney, *What Is Patent Quality? A Merchant Banc's Perspective*, 43 LES NOUVELLES 123, 130–31 (2008); Yasin Ozcan & Shane Greenstein, *Composition of Innovative Activity in ICT Equipment R&D*, 45 LOY. U. CHI. L.J. 479, 493 (2013); Michael Risch, *Patent Troll Myths*, 42 SETON HALL L. REV. 457, 477–80 (2012).

74. See Malackowski & Barney, *supra* note 73, at 131–30. More formally, a higher degree of citation (adjusted for time lag) should correspond with greater private value in the patent for its owner. We note a recent empirical study that challenges this empirical assumption. See David S. Abrams, Ufuk Akcigit & Jillian Popadak, *Patent Value and Citations: Creative Destruction or Strategic Disruption?* (Penn Inst. Econ. Res., Working Paper No. 13-065, Nov. 2013), <http://economics.sas.upenn.edu/system/files/13-065.pdf> [<http://perma.cc/D5EH-MZB3>] (finding that forward citation rates reflect growing private value only initially, but later correspond to strategic behavior aimed at preserving the returns from past patenting and to an overall decline in value). Though this study presents a compelling early criticism of the citation-value literature, its applicability is limited in important respects. The underlying data is based on the patent portfolios of non-practicing entities, whose reliance on licensing is a structurally different use of patent rights than by practicing entities such as manufacturers, who gain more from actually excluding competitors from the market than from merely threatening to exclude as leverage in a licensing negotiation. The underlying data is also proprietary, making it difficult to reproduce or even operationalize the findings into a more complete empirical model. This is not to suggest that the findings themselves are incorrect, but that further, replicable research is needed before the prevailing understanding of citations and value is properly discarded.

75. See Lee Fleming & Jasjit Singh, *Lone Inventors as Sources of Breakthroughs: Myth or Reality?*, 56 MGMT. SCI. 41, 54 (2010) (arguing that a larger team increases the likelihood of a breakthrough and decreases the likelihood of a relatively useless invention); Stefan Wuchty, Benjamin F. Jones & Brian Uzzi, *The Increasing Dominance of Teams in Production of Knowledge*, 316 SCIENCE 1036, 1036–37 (2007).

The citation literature has also generated quality proxies, such as technological originality and generality of the invention.⁷⁶ Despite the difficulty of separating out such general-purpose technology patents for analysis,⁷⁷ their presence in the background of so many different technologies makes them measurable in their influence and impact. Based on these insights, originality and generality have been discussed as correlate measures of patent quality.⁷⁸

Recent empirical analysis has shown, however, that examiners have a very significant influence on citations, and this influence is not randomly distributed.⁷⁹ Thus, it is unclear how citation data that pools applicant and examiner citations should be interpreted. Indeed, one study focused on variation among examiners found that examiners whose patents were subsequently *invalidated* by the Federal Circuit on average issued patents that were more frequently cited.⁸⁰

For our purposes, because we focus on the quality of incoming patent applications and of examination, the forward citation metric is not relevant. On the other hand, as further discussed below, numbers of backward citations to prior art perhaps intuitively address a basic sense of quality.⁸¹ Particularly relevant for our purposes, applicant-provided backward citations may be a proxy for the care with which the applicant drafted the application. In Part IV, we use applicant citations to prior art (both patents and non-patent literature) to evaluate incoming applications.

B. Private Value

The literature has often proxied for private value by looking at the characteristics of patents that are litigated or for which renewal fees are paid.⁸² In both cases, the assumption has been that rational parties would not incur associated expenditures without some expectation of

76. See generally Hall et al., *supra* note 73 (deriving these measures from analysis of time-adjusted citations).

77. In the context of software, the definition in most recent growing use relies on a detailed sorting at the level of U.S. patent class and subclass to mitigate over- and under-counting. See Graham & Vishnubhakat, *supra* note 62, at 75 n.7.

78. E.g., Josh Lerner, *The Litigation of Financial Innovations*, 53 J.L. & ECON. 807, 825 (2010).

79. Juan Alcácer, Michelle Gittelman & Bhaven Sampat, *Applicant and Examiner Citations in U.S. Patents: An Overview and Analysis*, 38 RES. POL'Y 415 (2009).

80. See Iain M. Cockburn, Samuel Kortum & Scott Stern, *Are All Patent Examiners Equal? The Impact of Characteristics on Patent Statistics and Litigation Outcomes*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 19, 22 (Wesley M. Cohen & Stephen A. Merrill eds., 2003).

81. Mann & Underweiser, *supra* note 71.

82. E.g., John R. Allison, Mark A. Lemley, Kimberly A. Moore & R. Derek Trunkey, *Valuable Patents*, 92 GEO. L.J. 435, 437–38 (2004); Kimberly A. Moore, *Worthless Patents*, 20 BERKELEY TECH. L.J. 1521 (2005).

a return on investment. This literature has determined that litigated and renewed patents generally have higher numbers of claims as well as higher rates of forward and backward citation.⁸³ Some commentators have therefore used number and complexity of claims not simply as a reflection of private value but also as a proxy for effort expended in obtaining the patent.⁸⁴ Similarly, in Part IV, we use number of claims at filing as a proxy for effort initially expended by the applicant.⁸⁵

Another important variable clearly correlated with private patent value is the size of the patent family — that is, the number of foreign jurisdictions in which the applicant has concurrently sought patent protection for the same invention.⁸⁶ We also rely on this variable in Part IV.

C. Legal Validity

A third body of work examines the extent to which a particular patent, examiner, or set of examination characteristics correlate with a subsequent finding of legal validity. For purposes of what the USPTO aims to do, the legal validity question is the most important. The validity metric is limited, however, by the very significant selection bias involved in cases that are litigated to a final validity determination by the Federal Circuit.⁸⁷ The patent-level characteristics that predict whether the small subset of patents litigated all the way to the Federal Circuit will be found valid or invalid may not necessarily predict outcomes with respect to the much larger pool of issued patents.⁸⁸

83. Allison et al., *supra* note 82, at 438; Moore, *supra* note 82, at 1530.

84. E.g., David S. Abrams & R. Polk Wagner, *Poisoning the Next Apple? The America Invents Act and Individual Inventors*, 65 STAN. L. REV. 517, 551 (2013).

85. Importantly, our use of the number of claims at filing is not a proxy for private value per se. The private value literature considers the number of claims at *issuance*, and restriction requirements by examiners to divide an application's claims into separate applications are particularly common in the fields of biotechnology and pharmaceuticals. As a result, the number of claims at filing may not reflect private value because such a number may differ from the number of claims at issuance. Yet the number of claims at filing does reflect an applicant's expectation, at the time of filing, of future private value in the patent — and so it is a reasonable proxy for applicant effort expended in producing a more detailed, higher-quality application. See Abrams & Wagner, *supra* note 84, at 551 (including the total number of claims in the empirical analysis, expecting “a higher-quality patent to be more detailed, and thus have more claims”).

86. See, e.g., Dietmar Harhoff, Frederic M. Scherer & Katrin Vopel, *Citations, Family Size, Opposition and the Value of Patent Rights*, 32 RES. POL'Y 1343 (2003).

87. See James Bessen & Michael J. Meurer, *Lessons for Patent Policy from Empirical Research on Patent Litigation*, 9 LEWIS & CLARK L. REV. 1, 4 (2005).

88. That said, there is no reason to believe that the factors that predict validity or invalidity in the subset of patents that reaches the Federal Circuit are strongly correlated with the factors that determine review by the Federal Circuit in the first instance. Mann & Underweiser, *supra* note 71, at 22–23.

Bearing this caveat in mind, it is nonetheless worth noting that one variable that is positively correlated with a finding of validity is applicant-submitted prior art references.⁸⁹ Indeed, the presence of applicant-submitted prior art references is a sufficiently prominent metric that some scholars have thoroughly analyzed applicant behavior across different technologies.⁹⁰ The evidence indicates that applications in certain technology areas benefit from much more applicant-supplied prior art than applications in other areas. For example, in a sample of patents issued between January 1, 2001 and December 31, 2003, 45% of patents in the computers/communications and electrical/electronic fields contained examiner-only citations compared to only 25% of drug and medical patents and 30% of chemical patents.⁹¹

D. Examiner Characteristics

An emerging body of literature examines the interaction between examiner characteristics and patent quality. Like the role of technology, the role of examiners in patent quality is complex. Because many aspects of an examiner's work are technology-specific, the examiner must at least be trained in a relevant science or engineering-related discipline.⁹² As a consequence, we would expect to see at least some variation in examiner characteristics. Indeed, as we discuss further in Part IV, such variation appears to be a key factor in our results.

Beyond subject matter, however, institutional incentives also result in considerable variation in examiner behavior — variation that has important implications for patent quality.⁹³ For example, experience level could affect quality, and the correlation might be either positive, because veteran examiners deliver more well-informed reviews, or negative, because beginning examiners pay greater attention to details than veterans. Experience also affects time allocated to examiners. Under a time allocation grid that has not been significantly

89. Mann & Underweiser, *supra* note 71, at 18.

90. Alcácer et al., *supra* note 79, at 419–20.

91. *Id.* The technological field effects were robust to nationality, assignee size, and other factors. *Id.* For further detailed analysis of prior art supplied by applicants at the time of filing, see generally Bhaven N. Sampat, *When Do Applicants Search for Prior Art?*, 53 J.L. & ECON. 399 (2010).

92. Examiners in the mechanical engineering field, for example, must be proficient in core subjects including differential and integral calculus, statics and dynamics, fluid mechanics and hydraulics, thermodynamics, electrical fields and circuits, properties and strengths of materials, and optics. See *Job Announcement No. CP-2014-0034*, USAJOBS (Mar. 21, 2014), <http://www.usajobs.gov/GetJob/ViewDetails/365088500> [<http://perma.cc/ZM6Z-HHE7>].

93. See Cockburn et al., *supra* note 80.

revised since 1976,⁹⁴ examiners at higher GS-levels within a given art unit are allocated substantially less time to review applications than examiners at lower GS-levels.⁹⁵ Time pressure could exacerbate any potential “burn out” felt by veterans.

Analysis at the individual examiner level is possible because, within an art unit, applications appear to be randomly assigned.⁹⁶ One complication, however, is the reality that multiple examiners within an art unit typically work on a single application. Primary examiners who have authority to issue actions in their own name supervise and sign off on the work of assistant examiners.⁹⁷ Supervisory patent examiners oversee the work of entire art units⁹⁸ in order to create more uniformity in examiner performance.⁹⁹

Despite this complication, some scholars have looked at individual examiner characteristics. In one study that attributed patent examination to the assistant examiner when there was one, and to the primary examiner if there was no assistant examiner, Professors Mark Lemley and Bhaven Sampat found that years of examiner experience at the USPTO at the time of patent examination correlated inversely with number of prior art references added and positively with grant rate.¹⁰⁰ More recently, Professors Michael Frakes and Melissa Wasserman, studying individual examiners as they moved up the GS-level ranks, found a similar trend in decreased examiner effort, and argued that it emerges from unduly stringent time constraints placed by the USPTO’s production quota system on higher-level examiners.¹⁰¹

94. *Patent Examiner Count System*, USPTO, <http://www.uspto.gov/patent/initiatives/patent-examiner-count-system> (last visited Dec. 17, 2015) (noting that “the last substantive change to the examiner goals was made over 30 years ago in 1976”).

95. Frakes & Wasserman, *supra* note 30. GS-level indicates General Schedule Pay Scale for various government employees.

96. See Mark A. Lemley & Bhaven Sampat, *Examiner Characteristics and Patent Office Outcomes*, 94 REV. ECON. & STAT. 817, 822 (2012).

97. U.S. Patent & Trademark Office, *Manual of Patent Examining Procedure* § 707.01 (9th ed. Rev. 7, Mar. 2014) [hereinafter MPEP].

98. See *Patent Technology Centers Management*, USPTO, <http://www.uspto.gov/patent/contact-patents/patent-technology-centers-management> (last visited Dec. 17, 2015) (listing supervisory patent examiners by art unit).

99. The effectiveness of these and related efforts at uniformity is the subject of ongoing discussion and improvement. See, e.g., Todd J. Zinser, *Memorandum for Director David J. Kappos on the USPTO Patent Quality Assurance Process (Final Report No. OIG-11-006-I)*, U.S. DEP’T OF COMMERCE OFFICE OF THE INSPECTOR GEN. (Nov. 5, 2010), <http://www.oig.doc.gov/OIGPublications/OIG-11-006-I.pdf> [http://perma.cc/T9XY-WZ78] (summarizing recommendations for improving the agency’s examination quality assurance standards). Notably, although the input of several different examiners into patent examination is a challenge for studies that rely on the individual examiner as the unit of analysis, it poses less of a challenge for our study, which takes the art unit as the unit of analysis.

100. Lemley & Sampat, *supra* note 96.

101. Frakes & Wasserman, *supra* note 30, at 3–5.

IV. BIOINFORMATICS AT THE USPTO: AN EMPIRICAL VIEW

This Part applies the quantitative patent quality literature discussed in Part III to an early cohort of patent applications from AU 1631 and a comparison group, AU 2123. We use the patent quality measures identified above both to evaluate applications coming into AU 1631 and AU 2123 and to isolate the effects of the examination process on these applications.

A. Technology and Comparison Group

In general, AU 1631 broadly covers inventions combining biology with computer implementation. The unit encompasses algorithms that predict gene function and protein folding and the application of *in silico* screening assays for identifying drug candidates.¹⁰²

To understand more precisely what the USPTO does and does not regard as bioinformatics technology, and why AU 2123 is a reasonable comparison group, it is helpful to compare two classification systems that the USPTO employs. One is the United States Patent Classification (“USPC”) system describing the technological fields to which inventions pertain.¹⁰³ The other is the USPTO Technology Center system, which describes the organizational division of art units that are responsible for patent examination.¹⁰⁴ When the USPTO receives a patent application, the Office of Patent Classification both categorizes it as to the technology class or classes that the claimed invention best represents and assigns it to the art unit best suited to examine it.¹⁰⁵ Not surprisingly, there is a close concordance between the USPC and the USPTO art unit hierarchy.¹⁰⁶ According to this

102. The unit excludes biomedical imaging and simulation of organ functioning.

103. The USPC is not the only technology classification system maintained by the USPTO — the International Patent Classification (“IPC”) system has long been in use as well, and the Cooperative Patent Classification (“CPC”) system is the most recent initiative for a harmonized taxonomy among the major patent systems. *Classification Standards and Development*, USPTO, <http://www.uspto.gov/patents/resources/classification> (last visited Dec. 17, 2015).

104. See generally *Patent Technology Centers*, USPTO, http://www.uspto.gov/about/contacts/phone_directory/pat_tech (last visited Dec. 17, 2015). They are also referred to as Patent Examiner Group Centers. See *Office of the Deputy Commissioner for Patent Operations*, USPTO, <http://www.uspto.gov/about-us/organizational-offices/office-commissioner-patents/office-deputy-commissioner-patent> (last visited Dec. 17, 2015).

105. See U.K. INTELL. PROP. OFFICE & U.S. PATENT & TRADEMARK OFFICE, PATENT BACKLOGS, INVENTORIES AND PENDENCY: AN INTERNATIONAL FRAMEWORK 18 (2013), <http://www.ipo.gov.uk/ipresearch-uspatlog-201306.pdf> [<http://perma.cc/JUM7-XB2G>] (noting that applications received by the patent office first undergo pre-examination formalities such as docketing and allocation according to relevant technology classification systems).

106. See *Patent Classification: Classes Arranged by Art Unit*, USPTO (Aug. 2015), <http://www.uspto.gov/patents-application-process/patent-search/understanding-patent->

concordance, bioinformatics inventions examined in AU 1631 are classified into subsets of U.S. patent class 703 pertaining to data processing.¹⁰⁷ Traditional software informatics inventions examined in AU 2123 are classified similarly.¹⁰⁸ The two art units do not overlap in the subclasses they cover. Between them, the art units cover class 703, as Table 1 summarizes.

Discussions with USPTO staff familiar with bioinformatics examination confirmed that AU 2123 is a closely complementary art unit to AU 1631. USPTO staff noted, for example, that examiners in the two art units sometimes share cases.¹⁰⁹ In addition, because the technology in each of the art units has been assigned the same class by the USPTO, an examiner at a given GS-level in AU 1631 is given the same amount of time to review an application as an examiner at the same GS-level in AU 2123.¹¹⁰

Table 1: U.S. Patent Classes and Subclasses Mapped to AUs 1631 and 2123

Class 703 (Data Processing: Structural Design, Modeling, Simulation, and Emulation)			
Subclass	Title	AU 1631	AU 2123
1	Structural Design		×
2	Modeling by Mathematical Expression		×
3	Electrical Analog Simulator		×
4	Of Electrical Device or System		×
5	Of Physical Phenomenon (e.g., Heat, Wave, Geophysics)		×
6	Simulating Nonelectrical Device or System		×
7	Mechanical		×
8	Vehicle		×

classifications/patent-classification.html (providing a crosswalk between the two taxonomies).

107. *Classes Arranged by Art Unit: Art Units 1611–1763*, USPTO, <http://www.uspto.gov/patents-application-process/classes-arranged-art-unit-art-units-1611-1763.html> (last visited Dec. 17, 2015).

108. *Classes Arranged by Art Unit: Art Units 1764–2691*, USPTO, <http://www.uspto.gov/patents-application-process/classes-arranged-art-unit-art-units-1764-2691.html> (last visited Dec. 17, 2015).

109. Interview with Marjorie Moran, AU 1631 Supervisory Patent Examiner, and George Elliott, former Technology Center 1600 Director (Oct. 19, 2013) (notes on file with author Arti K. Rai) [hereinafter Interview with Moran and Elliott].

110. See Rai, *supra* note 32, at 2062–63 (discussing allotment of time by GS-level and technology class).

9	Fluid		×
10	Well or Reservoir		×
11	Biological or Biochemical	×	
12	Chemical	×	
13	Simulating Electronic Device or Electrical System		×
14	Circuit Simulation		×
15	Including Logic		×
16	Event-Driven		×
17	Event-Driven		×
18	Power System		×
19	Timing		×
20	Target Device		×
21	Computer or Peripheral Device		×
22	Software Program (i.e., Performance Prediction)		×
23	Emulation		×
24	Of Peripheral Device		×
25	I/O Adapter (e.g., Port, Controller)		×
26	Of Instruction		×
27	Compatibility Emulation		×
28	In-Circuit Emulator (I.E., ICE)		×

However, though the technology in the applications allocated to the two art units is comparable, applications received in the two art units may not necessarily be comparable. As noted previously, drugs, medicine, and chemistry all represent areas where applicants have historically supplied significantly more prior art than in electronics and communications.¹¹¹ Whether or not bioinformatics applications resembled drugs, medicine, and chemistry in this respect was a proposition we tested.

In addition, we tested for differences in patent examination based on examiner characteristics at the level of the art unit. On average, patent examiners in the two art units differ in several ways that may be meaningful. Given AU 1631's biological sub-focus within informatics, examiners in that art unit are primarily trained in a biological science with additional relevant expertise in computer science, rather than primarily trained in computer science as AU 2123 examiners are.¹¹² USPTO staff also indicated that AU 1631 has more examiners

111. See *supra* Part III.C.

112. Interview with Moran and Elliot, *supra* note 109.

who hold advanced degrees than AU 2123: approximately 55% to 60% of AU 1631 examiners have Ph.D. degrees and up to 90% have master's degrees.¹¹³

In this regard, personnel data obtained through Freedom of Information Act ("FOIA") requests, and generously provided to us by Professor Ronald Mann, showed differences in the personnel in the respective art units. Specifically, the thirteen examiners in AU 1631 in calendar year 2003 had a median GS-level of 13 and had been at the USPTO for a median of four years.¹¹⁴ The sixteen examiners in AU 2123 had a median GS-level of 11.5 and had been at the USPTO for a median of two years.¹¹⁵

Finally, for reasons introduced in Part II.C and discussed further below, the particular legal details of examination may have been quite technology-specific. This was true not only because of practical differences in the definition of a PHOSITA¹¹⁶ and the relative unpredictability of the art,¹¹⁷ but also because of mechanisms by which USPTO guidelines and Federal Circuit case law, particularly in 2003, may have applied differentially to bioinformatics and "ordinary" software.¹¹⁸

In all, we were interested both in potentially divergent characteristics of applications as they entered the two art units, and divergent treatment that awaited them there. As to the latter question, even assuming comparable inputs, the literature led us to form several hypotheses about differential examination.

B. Hypotheses About Examination

First, we expected significant differences in treatment under the written description requirement of 35 U.S.C. § 112(a). Not long after the creation of AU 1631, the USPTO in early 2001 finalized its Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112 ¶ 1, "*Written Description*" Requirement.¹¹⁹ Although the guidelines did not, on their face, apply only to biotechnology, all of their examples came from biotechnology, and most of the relevant

113. *Id.*

114. FOIA-Requested USPTO Personnel Data (on file with author Arti K. Rai).

115. *Id.*

116. *See supra* notes 45–50.

117. *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970) (explaining that the scope of acceptable instruction in the patent varies inversely with the level of scientific or technological unpredictability that is involved).

118. *Supra* notes 46–49 and accompanying text (discussing divergent standards of sufficiency as to patentability based on the unpredictability of the field).

119. 66 Fed. Reg. 1099 (Jan. 5, 2001).

Federal Circuit case law at the time addressed biotechnology.¹²⁰ Thus, we expected more stringent application of the written description requirement to applications assigned to AU 1631. We further hypothesized that examiners would find it difficult to confine written description rejection to the strictly biological aspects of applications, and thus this stringent application would “spill over” into the “software” aspects of the invention — the net result being that applications would sometimes be rejected for failing to fully describe relevant algorithms and data.

Notably, we expected stricter application of the written description requirement, even though the literature on examiner characteristics discussed in Part III might lead us to believe that the higher GS-level examiners in AU 1631 would be *less* likely to administer a thorough examination. Our prediction was that higher education levels and clear expectations that written description should apply strictly to applications involving biotechnology would counteract any effects arising from examiner GS-level.

Second, we wanted to examine any differences in other aspects of the patent law that implicate notice — specifically: definiteness, double patenting, and restriction requirements. Here, we did not have a specific hypothesis but were motivated by the persistent criticism that software patents fail in their notice function.

Third, we expected examination in AU 1631 to more strictly apply the utility requirement of 35 U.S.C. § 101. At the same time it issued its Written Description Guidelines, the USPTO issued its Utility Examination Guidelines.¹²¹ Although these guidelines were nominally agnostic as to technology, they were written with biotechnology in mind.¹²² Thus, we expected more stringent application of the utility requirement to applications that claimed biotechnology-related inventions. Again, our prediction was that higher education levels and clear expectations of how to examine applications touching on biotechnology would counteract any effects arising from GS-level.

Fourth, we expected differences in treatment under both the enablement requirement of 35 U.S.C. § 112(a) and the nonobviousness requirement of 35 U.S.C. § 103. With respect to enablement, we predicted that the greater unpredictability of biotechnological arts and the impact of such unpredictability on what a person of ordinary skill in the art would consider enabled would lead to a higher rejection rate. Again, our prediction was that higher education levels and clear ex-

120. See Arti K. Rai, *Patent Validity Across the Executive Branch: Ex Ante Foundations for Policy Development*, 61 DUKE L.J. 1237 (2012) (discussing the tortured history of the written description and utility guidelines).

121. 66 Fed. Reg. 1092 (Jan. 5, 2001).

122. See Rai, *supra* note 120.

pectations of how to examine applications touching on biotechnology would counteract any effects of GS-level.

As for nonobviousness, we expected that the strict requirement that existed prior to 2007 for an examiner to identify teaching, suggestion, or motivation in order to combine prior art¹²³ would lead to a lower nonobviousness rejection rate for bioinformatics because of its interdisciplinary nature. This effect would arise on top of any difference in nonobviousness rejection rate caused by unpredictability in the field. In this case, GS-level effects might be a third factor leading to lower rates of nonobviousness rejection.

C. Results: Applications

To test our hypotheses and describe more fully the contours of USPTO bioinformatics examination early in its history, we reviewed by hand the prosecution histories of patent examinations that were filed between January 1 and December 31, 2003, and were assigned to AU 1631 or AU 2123. These examination records are publicly available from the USPTO Patent Application Information Retrieval (PAIR) system¹²⁴ as well as in bulk through Google¹²⁵ and, more recently, Reed Tech.¹²⁶

We chose calendar year 2003 because it represented the first year for which full prosecution history data on all applications were available on PAIR. Additionally, by 2003, AU 1631 had become reasonably well-established. However, at the same time, the application of software to biology was not yet considered entirely routine. Thus, for example, in 2003, bioinformatician Lincoln Stein famously gave bioinformatics “ten years to live,”¹²⁷ predicting that although informatics would continue to expand and be used, it would, within ten years, be absorbed into biology.¹²⁸

For each prosecution, we collected information on patent application characteristics, which, as the empirical literature discussed in Part III suggests, bears on one or more of the following: (1) scientific importance; (2) private value; and (3) legal validity. Specifically, we

123. This requirement was relaxed in *KSR Int'l Co. v. Teleflex Inc.* 550 U.S. 398, 401 (2007).

124. Patent Application Information Retrieval, USPTO, <http://portal.uspto.gov/pair/PublicPair> (last visited Dec. 17, 2015).

125. USPTO Bulk Downloads: Patents, GOOGLE, <http://www.google.com/googlebooks/uspto-patents.html> [<http://perma.cc/G6E2-KRP4>].

126. USPTO Data Sets, REED TECH. & SVCS. INC., <http://patents.reedtech.com/patent-products.php> [<http://perma.cc/HS33-MAEL>].

127. Daniel H. Steinberg, *Stein Gives Bioinformatics Ten Years to Live*, O'REILLY MEDIA (Feb. 5, 2003), <http://archive.oreilly.com/pub/a/network/biocon2003/stein.html> [<http://perma.cc/N397-DFWW>].

128. *Id.*

collected information on: (1) number of inventors (scientific importance); (2) number of claims; (3) family size; and (4) application and/or grant in the European Patent Office (“EPO”) and Japan Patent Office (“JPO”) (private value) and applicant-cited prior art, including Non-Patent Literature (“NPL”) (legal validity).

In total, we gathered data on 565 prosecution histories, 393 from AU 1631 and 172 from AU 2123. Univariate analysis was performed using unpaired two-tailed t-test for continuous variables and Fisher’s exact test for categorical variables. Significance was assessed using an alpha of 0.05. Table 2 illustrates the differences in these measures among applications in both art units. Virtually all the differences are statistically significant at the mean, as Table 2 shows.

Table 2: Two-Tailed Comparison of Means for Application and Examination Process Characteristics

Characteristic	Mean (AU 1631)	Mean (AU 2123)
Inventors ***	3.36	2.31
Claims ***	38.41	26.15
Applicant Cited Prior Art ***	30.17	8.72
Applicant Cited NPL ***	20.97	4.41
Family Size ***	3.05	2.26
Applied in EPO ***	0.48	0.26
Granted in EPO *	0.12	0.06
Applied in JPO	0.35	0.30
Granted in JPO *	0.09	0.17
Family Size ***	3.05	2.26

*p < 0.05; **p < 0.01; ***p < 0.001

Thus, notwithstanding the fact that both sets of applications involved software used for modeling and simulation, applications in AU 1631 were more scientifically important (number of inventors), privately valuable (numbers of claims, family size, and application in the EPO and JPO), and likely to be legally valid (applicant cited prior art, including NPL), than applications in AU 2123.

To some extent, our results on incoming patent applications are in line with, and reinforce, the theme of quality variation across patenting in different technologies that we discussed in Parts II.C and III.C. That said, the fact that such variation occurs even when the actual scientific difference between the technologies in question (software for biological modeling vs. general modeling software) is quite modest is striking.

D. Results: Examination

Although the disparity in application characteristics was not unexpected, it did indicate to us that we needed to create a new data set for purposes of testing examination results. Specifically, we decided to create a subset that consisted of a matched sample of applications in the two art units. We matched applications on the following variables:

- Number of inventors at filing;
- Number of claims at filing;
- Number of applicant-cited prior art references;
- Number of applicant-cited non-patent literature references;
- Patent family size;
- Whether concurrent application in the EPO was sought;
- Whether concurrent application in the EPO was granted;
- Whether concurrent application in the JPO was sought; and
- Whether concurrent application in the JPO was granted.

As to the latter four variables (pertaining to concurrent applications), pairs were matched directly. That is, an application from AU 1631 was required to have the same value (true vs. false) as the potential paired application from AU 2123. For the former five variables, pairs were quartile-matched. For example, an application from AU 1631 may have been in the first quartile of the distribution of number of inventors at filing for all AU 1631 applications. Such an application could be paired only with an application from AU 2123 that was also in the first quartile of the distribution of number of inventors at filing for all AU 2123 applications. Where multiple potential pairs existed that satisfied all matching criteria, pairs were assigned randomly.¹²⁹ This matched sample consisted of sixty-one applications in each art unit. The relatively small size of this matched sample may cause certain examination disparities between the samples to fail to reach statistical significance. Thus, to the extent we discuss only disparities that have statistical significance, we probably underestimate disparities.

129. We built the sets of potential pairs by hand in Excel and used that software's random number generator to assign pairs randomly.

With respect to the substance of examination, we collected information on the statutory grounds for rejections, the source of the prior art that the examiner cited in support of such rejections, and the examiner's imposition of a restriction requirement, if any, through the first round of examination.¹³⁰ Tables 3 and 4 illustrate our findings.

As these Tables show, examination in the two art units differed quite significantly. We discuss these differences in detail in the next section.

Table 3: Grounds for Rejection During Prosecution

Grounds	Proportion (AU 1631) n = 393	Proportion (AU 2123) n = 172	p-value
Subject-Matter Eligibility	40.97%	43.02%	0.6481
Utility	5.60%	0.58%	0.0055
Novelty	59.29%	55.81%	0.4411
Nonobviousness	52.67%	80.81%	0.0000
Enablement	24.68%	8.14%	0.0000
Definiteness	66.41%	54.65%	0.0078
Written Description	25.19%	8.14%	0.0000
Double Patenting	16.28%	5.81%	0.0007
Restriction	79.90%	8.72%	0.0000

Table 4: Source of Prior Art Used in Rejection¹³¹

Source	Proportion (AU 1631) n = 393	Proportion (AU 2123) n = 172	p-value
Prior Art Cited by the Examiner	44.53%	66.86%	0.0000
Prior Art Cited by the Applicant	7.38%	3.49%	0.0075
Prior Art Cited by Both	17.56%	27.91%	0.0052

130. A restriction requirement is an enforcement by the examiner of the single-invention rule and consists of a finding by an examiner that a patent application claims "two or more independent and distinct inventions," so that the applicant must restrict the application to one of them. 35 U.S.C. § 121 (2012). The applicant may then claim each remaining invention in a divisional application that otherwise satisfies the criteria for patentability. *See generally* 37 C.F.R. § 1.142 (2015); MPEP Ch. 0800 (9th ed. Rev. 7, Mar. 2014).

131. The values for each art unit do not add up to 100% because there were a number of applications in both samples (an especially large number in AU 1631) for which prior art was not a basis for rejection.

E. Discussion

1. Subject Matter

The rate at which bioinformatics applications in AU 1631 received rejections for subject matter ineligibility under § 101 (36.87%) was not significantly different from that of software applications in AU 2123 (42.62%).¹³² As we have discussed, given that bioinformatics and other informatics bear a general taxonomic similarity and differ only in their details.¹³³ Thus, it is perhaps unsurprising that the requirements of subject matter did not affect one group more than the other.

That said, subject matter is a rather coarse filter for evaluating inventions. Indeed, this view appears in the case law,¹³⁴ the literature,¹³⁵ and even legal guidance that the USPTO has issued in response to the Supreme Court's interpretation of § 101.¹³⁶ For a more fine-grained comparison, we turn to various patentability requirements under § 112 and § 103.

2. Written Description: Impacts on Notice

Supporting our first hypothesis, bioinformatics applications in AU 1631 did receive rejections for inadequate written description under § 112 to a significantly greater extent (21.30%) than did software applications in AU 2123 (6.56%).¹³⁷ Moreover, as we predicted, use of written description was not limited to the biological aspects of the invention; a check of the first fifteen written description rejections in AU 1631 for which we coded showed that thirteen of the fifteen rejections involved examiner arguments that the applicants had failed to describe adequately either an algorithm or relevant data.¹³⁸

132. See *supra* Table 3 (finding no statistically significant difference at the 95% confidence interval). Similarly, for novelty, the difference between rejections received for applications in AU 1631 (49.18%) and AU 2123 (55.74%), was not statistically significant. See *id.*

133. See *supra* Part IV.A.

134. *E.g.*, *Res. Corp. Tech., Inc. v. Microsoft Corp.*, 627 F.3d 859, 869 (Fed. Cir. 2010) (referring to § 101 as “the coarse eligibility filter”).

135. *E.g.*, Michael W. Carroll, *One for All: The Problem of Uniformity Cost in Intellectual Property Law*, 55 AM. U. L. REV. 845, 892–93 (observing that “use of standards along the subject matter dimension permits only coarse-grained exercise of interpretive discretion because an adjudicator can choose only between applying all or no rights to a particular innovation or class of innovations”).

136. *Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of Bilski v. Kappos*, 75 FED. REG. 43,922, 43,926 (July 27, 2010) (explaining that “Section 101 is merely a coarse filter”).

137. *Id.*

138. The written description rejections we examined arose in application numbers 10/204849, 10/304496, 10/309152, 10/309391, 10/332999, 10/345905, 10/350341,

As previously discussed, adequate written description requires disclosure of structure commensurate with the scope of what is claimed.¹³⁹ As a result, it may somewhat limit scope, perhaps unduly. The written description requirement's chief virtue is its promotion of boundary notice. In turn, certainty about patent boundaries offers a number of benefits including the ability to assess the value of patent rights for transaction and commercialization,¹⁴⁰ to "distinguish the invention or discovery from other things before known and used"¹⁴¹ in determining freedom to operate, and, most simply, to avoid infringement of a competitor's patents.¹⁴²

Taken in historical context, this finding as to bioinformatics inventions in AU 1631 and more conventional informatics inventions in AU 2123 suggests that the structural specificity that already existed for biological and biochemical inventions invited more robust examiner scrutiny of the relatively unstructured software elements of applications in AU 1631. The alternative inference is that applications on conventional software informatics inventions in AU 2123 received fewer written description rejections, because they were already better described under § 112. This inference, however, is inconsistent with the widely accepted view, discussed in Part II.C, that conventional software patents pose substantial challenges for notice. Moreover, as we discuss further in Part V, current patent notice reform efforts aimed at improving the correlation between functional claiming and corresponding structure also focus heavily on software.

3. Other Indicia of Notice

Our results also showed differences in examination with respect to other indicia of patent notice. Three measures in our results — definiteness, double patenting, and restriction — were particularly relevant in this regard. The definiteness requirement promotes boundary notice by requiring that patent claim terms clearly delineate *ex ante*

10352246, 10/359439, 10/360747, 10/360796, 10/363727, 10/432932, 10/430685, and 10/378866. Of these, only two (10/304496 and 10/359439) applied written description to the biological aspect of the invention.

139. See *supra* note 22 and accompanying text.

140. See generally Craig Allen Nard, *Certainty, Fence Building, and the Useful Arts*, 74 IND. L.J. 759 (1999). In advocating for opposition proceedings to test closely the validity of patents and provide early certainty, Professor Nard argues that such a proceeding "will facilitate greater accuracy in private valuation because, as the prior art picture becomes more complete during prosecution, the more informed the parties will be with respect to the boundaries of the claimed invention." *Id.* at 765–66.

141. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124–25 (2014) (citing the first Patent Act, Act of Apr. 10, 1790, § 2, 1 Stat. 110; the Act's call for definiteness in claims continues to animate patent law to the present day).

142. See *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008); *Laitram Corp. v. Cambridge Wire Cloth Co.*, 863 F.2d 855, 856–57 (Fed. Cir. 1988).

the metes and bounds of an invention as claimed in the patent.¹⁴³ The double patenting rule furthers this goal by exerting downward pressure on the sheer quantity of rights that a market actor must navigate and clear, particularly because the existence of duplicative patent rights injures the public's expectation that the expiration of a patent on an invention will leave that invention free for public use.¹⁴⁴ This rule recognizes that even if individual patent rights were perfectly clear *ex ante* — an assumption that is far from realistic — the discovery costs of identifying relevant rights¹⁴⁵ are also a function of scale. Put another way, if the capacity to search effectively does not survive increasing size and complexity in the set of all patent rights, then search bottlenecks may still cause notice failures.¹⁴⁶

Unlike definiteness and double patenting, which clearly promote notice, the single invention rule has more complex effects. On the one hand, it furthers notice by mitigating the complexity of patent rights in somewhat the same way that the definiteness requirement seeks to do. Whereas definiteness offers clarity in evaluating claims within a patent, restriction offers clarity in evaluating inventions within a patent. Examiners commonly impose restriction requirements in pharmaceutical-and biotechnology-related applications because it is common for applications in those fields to claim numerous related chemical compounds or processes that turn out to be patentably distinct.¹⁴⁷

That said, there is evidence that divisional applications occur not only among the least valuable patents, where applicant ignorance might be the cause, but also among the most valuable patents, suggesting that sophisticated applicants sometimes draft claims calculated to provoke restriction by the examiner.¹⁴⁸ This evidence may mean that applicants who draft claims calculated to provoke restriction sometimes intend to produce strategic delay in examination, and that

143. See *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779–80 (Fed. Cir. 2002) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28–29 (1997)).

144. *In re Longi*, 759 F.2d 887, 892–93 (Fed. Cir. 1985) (explaining that “[t]he public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent but also [obvious] modifications or variants”).

145. Discovery costs are one subset of the general transaction costs that Ronald Coase distinguished in his theory of externalities. See R. H. Coase, *The Problem of Social Cost*, 3 J.L. & ECON. 1, 15 (1960).

146. For a systematic overview of this principle, see generally Christina Mulligan & Timothy B. Lee, *Scaling the Patent System*, 68 N.Y.U. ANN. SURV. AM. L. 289 (2012).

147. Matt Browning, *Now You See Them, Now You Don't: The USPTO's Rules on Claims and Continuations*, 23 BERKELEY TECH. L.J. 247, 251 (2008).

148. See Stuart J. H. Graham & David C. Mowrey, *Submarines in Software? Continuations in US Software Patenting in the 1980s and 1990s*, 13 ECON. INNOVATION & NEW TECH. 443 (2004).

this practice is particularly common in biotechnology.¹⁴⁹ If so, restriction may actually hinder public notice by creating market uncertainty about whether later-issued patent rights may encumber sunk investments.¹⁵⁰ In any case, the paradox of the restriction requirement's notice benefit is that, by carving up multi-invention applications into patentably distinct sets of rights, the single invention rule actually increases the total set of rights to be searched and cleared,¹⁵¹ but it does so by reducing the patent-to-invention relationship to a simple one-to-one correspondence.¹⁵²

With respect to all three rejection grounds in our matched sample, the percentage of rejections in AU 1631 was higher. And on two of the three rejection grounds, the difference was statistically significant at the power of the study. With respect to indefiniteness, applications in AU 1631 received more rejections (62.30%) than did applications in AU 2123 (40.98%).¹⁵³ Second, with respect to the double-patenting rule, applications in AU 1631 received more than twice as many rejections (13.11%) than did applications in AU 2123 (4.92%),¹⁵⁴ although this second result was not statistically significant at the power of this study. Third, with respect to the single invention requirement of § 121 to manage the complexity of patent rights by limiting each patent to one invention,¹⁵⁵ applications in AU 1631 received an order of magnitude more rejections (70.49%) than did applications in AU 2123 (6.56%).¹⁵⁶

Unlike with written description, no specific USPTO guidance instructed examiners in AU 1631 to apply these other notice requirements vigorously. The reason for generally higher levels of rejection in AU 1631 is therefore not clear. It is possible that higher educational levels could have led examiners in AU 1631 to police notice more

149. Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U.L. REV. 63, 103 n.164 (2004).

150. *Id.* at 72–73 (discussing the relationship between examination delay and market uncertainty). Professors Lemley and Moore argue further that 18-month publication of pending applications after the 1999 AIPA may not meaningfully have improved transparency about pending applications, as publication is required only for applications that will also be filed abroad, where 18-month publication is the norm, meaning that U.S. publication reveals only what would have become publicly available regardless. *Id.* at 88–89.

151. *Supra* notes 145–46 and accompanying text.

152. Notably, the professed purpose of restriction practice is usually administrative convenience in patent examination. *See, e.g.,* *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1568–69 (Fed. Cir. 1996). The extent to which restriction practice actually strikes an efficient balance in patent notice is an open empirical question.

153. *See supra* Table 3.

154. *See supra* Table 3.

155. *See supra* note 130.

156. *See supra* Table 3.

vigilantly, despite the fact that examiners in AU 1631 were more time-constrained on average than examiners in AU 2123.¹⁵⁷

Supporting our third hypothesis, bioinformatics applications in AU 1631 received rejections for inadequate utility under § 101 much more frequently (8.20%) than the traditional software informatics applications in AU 2123 (0.00%).¹⁵⁸ Possibly the Utility Guidelines that the USPTO issued in 2001, requiring a specific assertion by the applicant of the utility of the claimed invention,¹⁵⁹ had some effect on examiners.

4. Enablement and Nonobviousness

The results did *not* support our hypothesis that bioinformatics applications in AU 1631 would receive significantly more rejections for inadequate enablement under § 112 (a) than would traditional software informatics applications in AU 2123.¹⁶⁰ Arguably, the most notable feature of the enablement results was the low frequency of these rejections across *both* art units. This low frequency is consistent with the view that enablement rejections are complex, fact-and prior art-intensive inquiries that time-and resource-constrained examiners are unlikely to favor.

Consistent with our hypothesis, applications in AU 2123 *did* receive significantly more rejections for obviousness (78.69%) than did applications in AU 1631 (39.34%).¹⁶¹ In general, across all three hundred ninety-nine AU 1631 prosecution histories that we analyzed, examiners conducted prior art searches in both biology and software in the majority of cases. However, given that bioinformatics was still an emerging interdisciplinary field as of 2003, and given that the relevant pre-*KSR* law at the time required a very specific teaching, suggestion, or motivation in the art in order to combine prior art references, examiners were apparently quite reluctant to combine life science and software prior art. This reluctance appeared even though the applications in question, which had an average of 3.36 inventors,¹⁶² presumably often included both inventors with biological and software skills.

157. This is assuming that the matched set of applications coming into the two art units had roughly similar attributes with respect to notice (an assumption that seems likely except that applications in AU 1631 may have been likely to have more problems with respect to multiple inventions in the same patent).

158. See *supra* Table 3.

159. 66 Fed. Reg. at 1092.

160. See *supra* Table 3.

161. *Id.*

162. See *supra* Table 2.

In Part V, we discuss further the policy implications of our findings for patent quality. We also discuss the normative question of how, in view of these empirical findings, patent applications on interdisciplinary, team-based inventions should be examined. We propose that the answer turns in part on when the interdisciplinarity of the field in question itself becomes relatively routine. In the case of bioinformatics, this may have occurred before 2003. However, given the Federal Circuit's pre-*KSR* demand of a written teaching, suggestion, or motivation requirement, examiners may have been reluctant to combine life science and software references.

V. POLICY IMPLICATIONS FOR PATENT QUALITY AND TEAM-BASED INNOVATION

Given our relatively specific empirical focus on two art units, we tread carefully when it comes to implications for the patent system as a whole. However, our results do have implications for two areas: patent quality and examination of team-based innovation.

A. Patent Quality

As for quality, our results suggest that some combination of examiner training and advanced educational background may have an impact on patent quality, particularly with respect to notice. Thus, efforts to train examiners, particularly in the use of the written description requirement, and in mechanisms by which patent applicants can be forced to specify the meaning of potentially problematic claim terms,¹⁶³ are likely to prove fruitful. Moreover, while the USPTO is unlikely to attract significant numbers of individuals with advanced degrees in most art units, training examiners in basic principles of scientific peer review may prove useful as well.

B. Team-Based Innovation

Our inquiry also has implications for patent examination in an era of team-based, interdisciplinary science. Scientific knowledge production is increasingly team-based; indeed team sizes have risen at an average rate of 15% to 20% per decade, and this increase appears in nearly all subfields of research and invention.¹⁶⁴ Patent applications

163. See Menell & Meurer, *supra* note 58 at 37–39.

164. Benjamin Jones, *As Science Evolves, How Can Science Policy?*, in 11 INNOVATION POLICY AND THE ECONOMY 103, 113 (Josh Lerner & Scott Stern eds., 2011).

have mirrored this shift. All areas of patenting have increased in team size over the past 25 years across all countries.¹⁶⁵

The recognition that knowledge production is increasingly team-based has prompted some scholars to call for a doctrinal shift away from the familiar legal reference point of a “person having ordinary skill in the art” (“POSITA”) to a “team having ordinary skill in the art” (“TOSITA”). In a 2002 article, for example, Joseph Meara suggested that in fields where advances are typically made in interdisciplinary teams, a team-based standard would be more appropriate than an individual standard.¹⁶⁶ Meara gave the example of implementing a Dutch auction on the Internet. In that example, a team consisting of a software engineer and a businessperson with MBA training would presumably have found the idea obvious, even though either individual alone might not have.

Although Meara’s proposal was promulgated prior to *KSR v. Teleflex*, the principles of that proposal apply with even greater force after *KSR*. In a 2011 article advocating an inducement standard for nonobviousness (under which patents would be granted only on those inventions that “would not be disclosed or devised but for the inducement of a patent”),¹⁶⁷ Michael Abramowicz and John Duffy endorsed making the inducement determination at the level of the inventive team.¹⁶⁸

We build upon this earlier work, but propose a slightly different approach. In our view, a team-based approach should be used when a field has become *routinely* interdisciplinary. This is because the very act of creating a team may be innovative when it brings two previously disparate fields together into a new combinatorial space. Moreover, although a patent grant may not always be a sign of true invention (for the reasons we have discussed at length), at least some of these patents were presumably granted at a time when the interdisciplinarity in question was still nascent.

Recent empirical work has begun to quantify this combinatorial process of invention. Notably, a new study of U.S. patent and technology classification records from 1790 to 2010 demonstrates that patenting over that time has been characterized not only (or even primarily) by the creation of new technological capabilities but by the increasingly complex combination of existing technological building

165. *Id.*; see also Zhenzhong Ma & Yender Lee, *Patent Application and Technological Collaboration in Inventive Activities: 1980–2005*, 28 *TECHNOVATION* 379, 388 (2008).

166. See Joseph P. Meara, *Just Who Is the Person Having Ordinary Skill in the Art? Patent Law’s Mysterious Personage*, 77 *WASH. L. REV.* 267, 293 (2002).

167. Michael Abramowicz and John F. Duffy, *The Inducement Standard of Patentability*, 120 *YALE L.J.* 1590, 1590 (2011) (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 11 (1966)).

168. *Id.* at 1615.

blocks.¹⁶⁹ Because the USPTO assigns relevant USPC classifications to each patent,¹⁷⁰ a patent's classes identify the distinct technologies that the inventor combined to produce the invention — and the combination identifies the particular interdisciplinarity at work in that instance of inventive activity.¹⁷¹ Historically, the rate at which new inventions have introduced new technological capabilities, representing new technological classes, has slowed considerably.¹⁷² Yet surprisingly, the rate at which new *combinations* of technological classes have emerged has systematically kept pace with the number of new patents.¹⁷³

These results suggest that whereas some inventions represent new combinations of technological capabilities, other inventions represent merely existing combinations of technological capabilities. The former shows emerging interdisciplinarity; the latter, routine investigation within an increasingly well-defined field. A prior empirical study demonstrated that there is a 60% likelihood that a given invention augurs a new technological combination and only a 40% likelihood that it relies on an existing technological combination.¹⁷⁴ Thus, interdisciplinarity is, and historically has been, the prevailing mode of innovation.

To be sure, our proposed doctrinal inquiry of routine interdisciplinarity may sometimes prove difficult to implement. Beyond the ordinary line-drawing problems that inform all such taxonomic determinations, there is the added temporal difficulty of determining when previously unrelated disciplines should be regarded as solidly linked.

In the particular case of bioinformatics, we proceed with the benefit of a historical record. The systematic collection and analysis of biological sequence data has commanded the collaborative efforts of “computer scientists, statisticians, and biologists” for over four decades,¹⁷⁵ and the term “bioinformatics” itself dates from 1970.¹⁷⁶ The idea of a bioinformatician proper, however, is of more recent vintage, dating between the mid-1990s¹⁷⁷ and the early 2000s.¹⁷⁸ During this

169. Hyejin Youn et al., *Invention as a Combinatorial Process: Evidence from US Patents*, 12 J. ROYAL SOC'Y INTERFACE 20150272, at *3 (2015), <http://rsif.royalsocietypublishing.org/content/12/106/20150272.full-text.pdf> [<http://perma.cc/2P4M-7ERF>].

170. See *supra* note 103 and accompanying text.

171. Youn et al., *supra* note 169, at *3–4.

172. *Id.* at *4.

173. *Id.*

174. *Id.* at *5.

175. Andrew Chin, *Research in the Shadow of DNA Patents*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 846, 894 (2005).

176. Paulien Hogeweg, *The Roots of Bioinformatics in Theoretical Biology*, 7 PLOS COMPUT. BIOL. e1002021 at *1 (2011).

177. See Contreras, *supra* note 6 and accompanying text.

time, public accounts began referring to bioinformatics as its own field.¹⁷⁹ Moreover, universities, such as the University of Michigan¹⁸⁰ and the University of California San Diego,¹⁸¹ began establishing training and degree programs in bioinformatics.¹⁸²

To the extent of its authority, the USPTO worked to stay abreast of this shift toward team-based scientific research. The agency established its art unit in bioinformatics precisely as the fields of biology and software were becoming solidly linked. Indeed, as previously noted, by the year 2003 (the year that we studied), the role of computer science in biology was sufficiently well-established that Lincoln Stein predicted bioinformatics had only “ten years to live” as a field that could be considered interdisciplinary in the first instance.¹⁸³ However, the shadow of the Federal Circuit’s very exacting requirements for combining prior art may have kept AU 1631 from fully assimilating team-based research norms and practices. This intuition could be tested, at least to some extent, by analyzing the frequency of obviousness-based rejections in AU 1631 after the Supreme Court decision in *KSR v. Teleflex*.

VI. CONCLUSION

The empirical data on bioinformatics examination that this Article has presented may offer important contributions to the literature on patent quality. We have shown that patent applications in bioinformatics generally received more stringent examiner scrutiny and more rejections, particularly on notice-related grounds, than did applications in conventional software informatics. Bioinformatics examiners paid significant attention to notice not only in the biological aspects of the inventions that they examined, but also in the inventions’ strictly in-

178. See Charles Vorndran & Robert L. Florence, *Bioinformatics: Patenting the Bridge Between Information Technology and the Life Sciences*, 42 IDEA 93, 126 (2002) (noting that “bioinformatics is a multidisciplinary field” and that “the field, itself, is fairly new, yet developing rapidly”).

179. E.g., Brad Stone, *Wanted: Hot Industry Seeks Supergeeks*, NEWSWEEK (Apr. 29, 2001), <http://www.newsweek.com/wanted-hot-industry-seeks-supergeeks-150551> [<https://perma.cc/642P-ZGM7>].

180. UNIVERSITY OF MICHIGAN, *U-M Bioinformatics Graduate Program*, DEPARTMENT OF COMPUTATIONAL MEDICINE & BIOINFORMATICS, <http://www.ccmb.med.umich.edu/graduate-program> [<http://perma.cc/VVA5-63XR>] (dating the first class to 2001).

181. UNIVERSITY OF CALIFORNIA AT SAN DIEGO, *Bioinformatics and Systems Biology Graduate Program*, UC SAN DIEGO, <http://www.ucsd.edu/catalog/curric/BIOI-gr.html> [<http://perma.cc/E8ZN-35B8>] (dating the program’s founding to 2001).

182. Stone, *supra* note 179 (noting that, as of 2001, schools including the University of California Davis, the University of California Berkeley, and Cornell University had established bioinformatics programs or were planning to do so).

183. Steinberg, *supra* note 127.

formational aspects. Our results suggest that institutional investment in human capital and educational training can make a difference.

Our results did not hold, however, for application of the nonobviousness requirement before the *KSR* decision. *KSR* may therefore have been a particularly important precedent for proper evaluation of interdisciplinary and team-based science.

Our Article also offers the first empirical account of patent quality at the juxtaposition of two fields generally believed to be wholly opposed with respect to patent quality, particularly boundary notice. At the stage of initial application, we found significant evidence that bioinformatics applications were “better” than conventional informatics applications.

Finally, our results invite further study of invention that is conducted in collaborative environments and draws on expertise in a variety of disciplines, as bioinformatics does. A richer empirical account of these inventive activities would do much to align the U.S. patent system with the modern realities of team-based innovation.